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Digital Leader SMART PointNix

3F, Ace Twin Tower 1, 212-1, Kuro-Dong, Kuro-Ku, Seoul, Korea
Tel: 82-2-854-8315 / Fax: 82-2-839-4973

510(K) SUMMARY

JAN 2 4 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 5I0(k) number is K121800.
Date: January 17, 2013

1. Submitter's Identification:

PointNix Co., Ltd.
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2. Name of the Device:

Dental Digital X-ray Imaging Device models Point 500HD and Point 500C HD.

3. Common or Usual Name:

Usual Name : Dental Digital X-ray Imaging System
Classification : Class II
21 CFR 872.1800 System, x-ray, extraoral source, digital
Class Code : MUH

4. Predicate Device Information:

The Yoshida Dental MFG. Co., LTD.: Panoura 18S – K111231

5. Device Description:

The Point 500 HD/500C HD is a dental panoramic/panoramic and cephalometric device which is digital X-ray imaging device. It is intended for dental radiographic examinations of teeth, jaw and TMJ areas by exposing X-ray and then converts this information to the digital signals to acquire images. High-defined images are provided by controlling acquired image with computer and this is used to obtain panoramic and cephalometric images for dental purpose. This equipment is

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equipped with an X-ray generator and Sensor for panoramic and cephalometric at Rotation unit which are supported by Main frame and Column. When rotation unit is rotating around the patient's teeth and jaw for acquiring panoramic image, X-ray exposes and sensor detects the data from X-ray generator. Detected data from each frame is transferred to PC, and combined together to display panoramic image on PC screen by installed software on PC.

6. Intended Use:

Point 500 HD/500C HD which is the dental panoramic/panoramic and cephalometric device is intended to produce diagnostic quality radiographic images by acquiring digital 2D X-ray images. The cephalometric system produces cephalomertric radiographic images that maybe used in orthodontic diagnosis procedures.

7. Comparison to Predicate Devices:

Model / Characteristic	Proposed : Point 500HD, Point 500C HD	Predicated : Panoura 18S
510(k) Number	-	K111231
Intended Use	Point 500 HD/500C HD which is the dental panoramic/panoramic and cephalometric device is intended to produce diagnostic quality radiographic images by acquiring digital 2D X-ray images. The cephalometric system produces cephalomertric radiographic images that maybe used in orthodontic diagnosis procedures.	The Panoura 18S dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images. The device must only be operated and used by dentist and other legally qualified professionals.
Tube Voltage	50-90kV	58-82kV
Tube Current	4-16mA	2-10mA
Focal Spot Size	0.5 x 0.5 mm	0.5 x 0.5 mm
Scan Time	Only Panorama Mode(Point 500HD) : 16sec, Added cephalo Mode(Point 500C HD) : 0.8sec	Panorama Mode: 16sec Cephalo Mode: 10sec

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8. Statement of substantial equivalence

The characteristics of the Point 500HD/500C HD are similar to those of the Panoura 18S (K111231) listed below:

- Intended use
- Operating characteristics
- Radiation

Difference between Point 500HD/500C HD and Panoura 18S (K111231) is listed below:

- Detector type

This difference of detector does not raise any new safety or effectiveness concerns compared to the Panoura 18S (K111231).

9. Discussion of Non-Clinical Tests Performed:

Electrical, mechanical, environmental safety and performance testing according to standards EN/IEC 60601-1, EN/IEC 60601-1-3, EN/IEC 60601-2-7, EN/IEC 60601-2-28, and EN/IEC 60601-2-32 were performed, and EMC testing was conducted in accordance with a standard EN/IEC 60601-1-2. All test results were satisfactory.

10. Discussion of Clinical Tests Performed:

Not Required

11. Conclusions:

The PointNix Co., model Point 500HD and Point 500C HD have been developed and validated according to all applicable standards. Evaluations have proven that the system is safe and effective for the intended use. Risk analysis and safety certifications reveal that there is no new safety issues associated with this system as compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 24, 2013

PointNix Company, Limited
C/O Mr. Jigar Shah
MDI Consultants, Incorporated
#302~303, 3F, Ace Twin Tower 1, 212-1,
Kuro-Dong Kuro-Ku, Seoul, Korea

Re: K121800
Trade/Device Name: Dental Digital X-ray imaging system point 500 HD and point 500C HD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: II
Product Code: MUH
Dated: January 10, 2013
Received: January 15, 2013

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121800

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Section 2: Indications for Use

510(k) Number (if known): K121800

Device Name: PointNix Co., Ltd. Dental Digital X-ray Imaging System Point 500 HD and Point 500C HD

Indications For Use:

Point 500 HD/500C HD which is the dental panoramic/panoramic and cephalometric device is intended to produce diagnostic quality radiographic images by acquiring digital 2D X-ray images. The cephalometric system produces cephalomertric radiographic images that maybe used in orthodontic diagnosis procedures.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.24 15:22:50 -05'00'

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121800